

National Research Ethics Service

North West 9 Research Ethics Committee - Greater Manchester West

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7821

14 May 2010

Dr Emily Pattison
BILAG Biologics Register Study Coordinator
Arthritis Research UK Epidemiology Unit
The University of Manchester
Rutherford House
Manchester Science Park
40 Pencroft Way
Manchester
M15 6SZ

Dear Dr Pattison

Study title:	BILAG Biologics Prospective Cohort: The Use of Novel Biological Therapies in the Treatment of Systemic Lupus Erythematosus (SLE).(Lay title: Long-term Safety of New Biologic Treatments in the Management of SLE)
REC reference:	09/H1014/64
Protocol number:	1.3
Amendment number:	1 Minor
Amendment date:	30 March 2010

Thank you for your letter of 08 February 2010, notifying the Committee of the above amendment.

The amendment has been considered by the Chair.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Participant Information Sheet: Adult	3	08 February 2010
Participant Information Sheet: Parents	3	08 February 2010
Protocol	1.3	08 February 2010
Notification of a Minor Amendment	1	30 March 2010
Participant Information Sheet: Child	3	08 February 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/H1014/64:	Please quote this number on all correspondence
---------------------	---

Yours sincerely



Miss Shehnaz Ishaq
Committee Co-ordinator

E-mail: shehnaz.ishaq@northwest.nhs.uk

Copy to: Karen Shaw, R&D Department
The University of Manchester

Professor Ian Bruce
Professor of Rheumatology
Arc Epidemiology Unit,
Stopford Building
Oxford Road, Manchester
M13 9PL

Dr Lynne Webster R&D Department Central Manchester and
Manchester Children's University Hospitals NHS Trust